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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/718,754	11/22/2000	Kathryn K. Lappegard	1189	3443

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EXAMINER

BAUM, STUART F

ART UNIT PAPER NUMBER

1638

DATE MAILED: 02/13/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/718,754	Applicant(s) LAPPEGARD ET AL.	
	Examiner Stuart F. Baum	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6,21,40,41,44 and 45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2, 6, 21,40,41,44 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-2, 6, 21, 40-41, and 44-45 are pending.

Claims 11, 17, 42, and 43 have been canceled.

Claims 1, 2, 6, 21, 40, and 41 have been amended.

RCE Acknowledgment

2. The request filed on December 27, 2002 in paper no. 14 for a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114, based on parent Application No. 09/718754 is acceptable and a RCE has been established. An action on the RCE follows.

Specification

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See for example page 21, line 22. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 2, 6, 21, 40, 44, and are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 2, 21, and 40, the phrase, “and that drive(s) expression in” should be changed to “and that drive(s) expression of”.

In claims 1, 21, 44, and 45, the metes and bounds of “functional fragment” has not been defined. It has not been specified what is the function of the fragment, nor has Applicant described all the possible fragments which are being claimed.

Claim 6 is indefinite in the recitation “comprises a nucleotide sequence set forth in SEQ ID NO:1”. The indefinite article “a” signifies more than one possible nucleotide sequence. Amending the claim to recite “comprising the nucleotide sequence of SEQ ID NO:1” will obviate the rejection.

Claims 1, 2, 21, and 40 are indefinite in the recitation “maize Jip1”. The promoter of maize Jip1 has not been specifically defined. Amending the claims to recite “maize Jip1 of SEQ ID NO:1” will obviate the rejection.

Written Description

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 21, 40-41, and 44-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The inventors claim an isolated promoter comprising a functional fragment of the nucleotide sequence set forth in SEQ ID NO:1. Using the Genome Walker Kit, Applicants

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isolated a 5' region of the Jasmonate Induced Protein1 (Jip1) gene promoter from the maize line V3-4 A63 which was used as a probe for isolating a clone from the BAC library made from Mo-17 genomic DNA. They eventually amplified a 1.4 kb upstream piece of DNA which they subcloned into a vector containing the GUS gene with the pinII terminator (i.e. making the construct Jip1::GUS::pin II). The expression pattern of the endogenous gene was analyzed using Northern analysis.

The Applicants do not identify structural features unique to a maize Jip1 promoter that would define or describe 'functional fragments' of DNA that differ from SEQ ID NO:1, yet retain the maize Jip1 spatial and temporal expression pattern. The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. Given the lack of description for a maize Jip1 promoter, it remains unclear what features identify a maize Jip1 promoter, and what fragments of SEQ ID NO:1 that constitute a 'functional fragment'. Since a maize Jip1 promoter has not been described by specific structural features or by specific function, the specification fails to provide an adequate written description to support the claims directed to 'functional fragments' of SEQ ID NO:1.

Scope of Enablement

6. Claims 1, 21, 40-41, and 44-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to the 1247 bp's of SEQ ID NO:1, located 5' of an isolated maize Jip1 coding region, operably linked to a desired gene and transformed into a maize plant, to obtain expression in 15-40 days-after-pollination (DAP) embryos with some weaker expression in the endosperm and pericarp (page 31, first paragraph) does not reasonably provide enablement for claims broadly drawn to a functional fragment of the nucleotide sequence set forth in SEQ ID NO:1, for obtaining expression in 15-40 DAP embryos with some weaker expression in the endosperm and pericarp. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to a functional fragment of SEQ ID NO:1 however, the instant specification, fails to provide guidance for which base of SEQ ID NO:1 can be altered and still maintain proper spatial and temporal seed-preferred expression. The specification also fails to provide guidance for which base can be deleted and which regions of the sequence can tolerate additions, base-substitutions or recombinations and still be a functional promoter. Applicants have not taught what is the function of the 'functional fragment' nor how one would assay the activity of the 'functional fragment'. In addition, Applicants have not provided guidance for how one skilled in the art would make and/or use the claimed 'functional fragment'.

Using pieces of a promoter that do not contain the full compliment of cis-acting elements, will not produce the expression profile as observed using the whole promoter fragment. Kagaya et al (1995, Mol. Gen. Genet. 248 :668-674) teach the rice chloroplastic aldolase promoter

contains two elements, one of which acts as a negative element while the other acts as a positive element that confers developmentally regulated mesophyll cell specific expression. Removal of either of these regions changes the normal expression pattern (page 670, left column). Kagaya et al also teach that the promoter contains an element that serves as a target for light induction (abstract).

Benfey et al (1990, Science 250:959-966) teach that the 35S CaMV promoter consists of domains that individually regulate spatial expression within plants. "The combination of each of the five B subdomains with domain A results in an expression pattern that differs from that of the individual subdomains or domain A" (page 961, left column, 2nd paragraph). In other words, deleting a required domain will jeopardize the proper spatial and temporal expression pattern. In addition, Benfey et al (1989, EMBO J, 8(8):2195-2202; page 2200, left column 2nd paragraph) teach that not only are the promoter domains important for specifying proper spatial and temporal expression but that when all domains were present, the quantity of expression increased.

Given the unpredictability of determining the function of an isolated nucleic acid other than the 1247 bp's of SEQ ID NO:1, located 5' of the isolated maize Jip1 coding region, on the basis of its nucleotide sequence alone and the unpredictability of isolating a fragment of SEQ ID NO:1 whose function is the same as that of SEQ ID NO:1 as a whole, for the reasons stated above; given the lack of working examples of other maize Jip1 promoter sequences or fragments of SEQ ID NO:1 that have seed preferred promoter activity and lack of guidance of isolating other Jip1 promoters or a fragment of SEQ ID NO:1 from the multitude of sequences that are encompassed in SEQ ID NO:1 and assaying its promoter function; given the state-of-the-prior art

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which does not provide further guidance about Jip1 promoter regions and given the breadth of the claims which encompass a multitude of sequences that have not been exemplified, it would require undue experimentation by one skilled in the art to make and/or use the claimed invention.

7. SEQ ID NO:1 is deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of SEQ ID NO:1

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart Baum whose telephone number is (703) 305-6997. The examiner can normally be reached on Monday-Friday 8:30AM – 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 or (703) 305-3014 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, who may be contacted at 308-0196.

Stuart F. Baum Ph.D.

February 5, 2003


ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1800